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#### REMARKS UNDER 37 CFR § 1.111

### **Formal Matters**

Claims 1, 12, 13, 46, 53, 58 and 190-216 are pending after entry of the amendments set forth herein.

Claims 1, 12, 13, 21, 46, 53, 58 and 190-213 were examined. Claims 1, 12, 13, 21, 46, 53, 58 and 190-213 were rejected.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

### **The Office Action**

## Claims Rejected Under 35 U.S.C. Section 112, second paragraph

In the Official Action of March 16, 2006, claims 190-211 were rejected under 35 U.S.C. Section 112, second paragraph, as being indefinite. Regarding claim 190, the Examiner indicated that the recitation of the term "means" was indefinite. In response thereto, Applicants have amended claim 190 to change "means" to –member--. Regarding claim 211, Applicants have changed the dependency thereof from "203" to –205—to correct the antecedent basis problem.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 190-211 under 35 U.S.C. Section 112, second paragraph, as being indefinite, as being no longer appropriate.

# Claims Rejected Under 35 U.S.C. Section 101 – U.S. Patent No. 6,743,169

Claims 12, 13, 53 and 58 were rejected under 35 U.S.C. Section 101 as claiming the same invention as that of claims 2, 3, 4 and 5, respectively, of U.S. Patent No. 6,743,169. In view of the above amendment of claim 1 and since claims 12, 13, 53 and 58 depend from claim 1, Applicants respectfully submit that this ground of rejection is no longer appropriate.

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In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 12, 13, 53 and 58 under 35 U.S.C. Section 101, as being no longer appropriate.

# <u>Claims Rejected Under Judicially Created, Non-Statutory Double Patenting – U.S. Patent No. 6,743,169</u>

Claim 1 was rejected under the judicially created doctrine of double patenting, as being unpatentable over claims 2, 4 and 5 of U.S. Patent No. 6,743,169. The Examiner asserted that the subject matter of claim 1 is fully disclosed in the patent and is covered by the patent as the difference between the instant claim 1 and claims 2,4 and 5 of the patent lies in the fact that the patent claims include more elements than the instant claim 1. In response thereto, Applicants note that claim 1 has been amended above to further recite "means for introducing a positive or negative fluid pressure to said contact member, wherein introduction of said positive of negative fluid pressure fixes a present shape of the contact member". It is respectfully submitted that the claims of the patent do not include this recitation. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of claim 1 under this ground of rejection as being no longer appropriate.

Claims 212 and 213 were rejected under the judicially created doctrine of double patenting, as being unpatentable over claims 31 and 32 of U.S. Patent No. 6,743,169. The Examiner asserted that the subject matter of the instantly rejected claims is fully disclosed in the patent and is covered by the patent, since the patent and the present application are claiming common subject matter. The Examiner asserted that the difference between the application claims and the patent claims is that the patent claims include more elements and are thus much [more]specific. In response thereto, Applicants note that claim 212 has been amended above to further recite that the at least one continuously adjustable contact member is manipulated to adjust a shape of a contact surface of the contact member into a desired configuration, wherein the contact surface is configured to contact the surface of the heart; and that this recitation is not included in either claim 31 or 32 of the patent. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 212-213 under this ground of rejection as being no longer appropriate.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 190-209 and 211-213 under the judicially created doctrine of double patenting, as being unpatentable over claims of U.S. Patent No. 6,743,169, as being

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no longer appropriate.

# Claims Rejected Under 35 U.S.C. Section 102(e) (Vierra et al.)

Claims 1, 21, 46, 190 and 193 were rejected under 35 U.S.C. Section 102(e) as being anticipated by Vierra et al., U.S. Patent No. 5,749,892.

With regard to claim 1, the Examiner asserted that Vierra et al. discloses a device comprising means for stabilization a portion of the heart that comprises contact member 15, 17 shaped to engage the surface of the heart. Claim 1 has been amended above to further recite "means for introducing a positive or negative fluid pressure to said contact member, wherein introduction of said positive of negative fluid pressure fixes a present shape of the contact member". It is respectfully submitted that Vierra et al. fails to disclose or suggest this feature.

With regard to claim 21, claim 21 has been canceled above, without prejudice.

With regard to claim 46, the Examiner asserted that the contact members of Vierra et al. are malleable and can be adjusted. Without acquiescing to this assertion, it is respectfully submitted that claim 46 is dependent from claim 1 and is allowable for at least the same reasons that claim 1 is allowable.

With regard to claim 190, Vierra et al. fails to disclose at least one continuously adjustable contact member comprising a flexible tube that is adapted to be adjusted to a shape to substantially conform to a surface of the heart, wherein said shape is maintained by the device.

Claim 193 has been canceled without prejudice.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 46 and 190 (claims 21 and 193 having been canceled without prejudice) under 35 U.S.C. Section 102(e) as being anticipated by Vierra et al., U.S. Patent No. 5,749,892, as being inappropriate.

# Claims Rejected Under 35 U.S.C. Section 102(e) (Borst et al.)

Claims 1, 21, 190, 192, 203, 204, 212 and 213 were rejected under 35 U.S.C. Section 102(e) as being anticipated by Borst et al., U.S. Patent No. 5,836,311.

The Examiner asserted that Borst et al. discloses a device comprising a stabilizing means 13 comprising contact members 81,82 shaped to engage the surface of the heart and attached to shaft 80.

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However, Applicants respectfully submit that Borst et al. fails to disclose "means for introducing a positive or negative fluid pressure to said contact member, wherein introduction of said positive of negative fluid pressure fixes a present shape of the contact member", as now recited in instant claim 1.

With regard to claim 190, Borst et al. fails to disclose at least one continuously adjustable contact member comprising a flexible tube, wherein the at least one continuously adjustable contact member is adapted to be adjusted to a shape to substantially conform to a surface of the heart and is maintained in that shape by the device.

With regard to claim 192, the Examiner asserted that negative air pressure may be introduced to the contact members of Borst et al. However, claim 192 recites that application of vacuum substantially fixes the contact member in a currently adjusted shape. Borst et al. does not teach or disclose this feature.

As to claims 212 and 213, the Examiner asserted that Borst et al. discloses a method of preparing a device wherein the contact member is manipulated into a desired configuration and a vacuum is applied to the contact member. The Examiner referred to column 5, lines 1-7 of Borst et al. Claim 212, as amended, recites that the shape of the contact surface of the contact member is adjusted to a desired configuration. Borst et al. does not disclose or suggest modifying the shape of the contact surface, as only the neck 71 may be bent to change the orientation of the paddle 22.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 190, 192, 203, 204, 212 and 213 (claim 21 having been canceled without prejudice) under 35 U.S.C. Section 102(e) as being anticipated by Borst et al., U.S. Patent No. 5,836,311, as being inappropriate.

# Claims Rejected Under 35 U.S.C. Section 102(e) (Del Rossi et al.)

Claims 1, 46, 190, 191, 203 and 204 were rejected under 35 U.S.C. Section 102(e) as being anticipated by Del Rossi et al., "A New Retractor to Aid in Coronary Artery Surgery".

The Examiner asserted that Del Rossi et al. discloses a device for stabilizing comprising a stabilizing means having contact members shaped to engage the surface of the heart, and which are attached to a shaft. The Examiner further asserted that the contact members are malleable and form a Ushape.

However, Applicants respectfully submit that Del Rossi et al. fails to disclose "means for introducing a positive or negative fluid pressure to said contact member, wherein introduction of said

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positive of negative fluid pressure fixes a present shape of the contact member", as now recited in instant claim 1.

With regard to claim 190, Del Rossi et al. fails to disclose at least one continuously adjustable contact member comprising a flexible tube, wherein the at least one continuously adjustable contact member is adapted to be adjusted to a shape to substantially conform to a surface of the heart and is maintained in that shape by the device.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 46, 190, 191, 203 and 204 were rejected under 35 U.S.C. Section 102(e) as being anticipated by Del Rossi et al., "A New Retractor to Aid in Coronary Artery Surgery", as being inappropriate.

# **New Claims**

It is respectfully submitted that none of the art of record teaches, discloses or suggests the present invention as recited in new claims 214-216, as presented above. Further in this regard, it is respectfully submitted that none of the art of record, whether taken singly or in any proper combination, teaches, discloses or suggests a device for use in cardiovascular surgery on the beating heart, comprising: a shaft member having a distal end portion and a proximal end portion; and at least one continuously adjustable contact member connected to said distal end portion of said shaft member, said at least one continuously adjustable contact member comprising a wire configured to be adjusted to substantially conform a contact surface of said contact member to a surface of the heart, as recited in new claim 214.

It is respectfully submitted that none of the art of record, whether taken singly or in any proper combination, teaches, discloses or suggests a device for use in a cardiovascular surgery on the beating heart comprising: a means for stabilizing the beating heart comprising a contact member including a shape memory material and shaped to engage the surface of the beating heart, as recited in new claim 215.

It is respectfully submitted that none of the art of record, whether taken singly or in any proper combination, teaches, discloses or suggests a device for use in cardiovascular surgery on the beating heart, comprising: a shaft member having a distal end portion and a proximal end portion; and at least one continuously adjustable contact member connected to said distal end portion of said shaft member, said at least one continuously adjustable contact member adapted to be adjusted to a shape to

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substantially conform a contact surface of said contact member to a surface of the heart, as recited in new claim 216.

## **Conclusion**

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-2653, order number GUID-005CON6.

Respectfully submitted, LAW OFFICE OF ALAN W. CANNON

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